Amendments to the Drawings

Submitted herewith and attached hereto are amended drawings, specifically Figs. 2 – 4, which correctly identify the figures as Figs. 2A and 2B, 3A and 3B, 4A and 4B. The amended drawings are labeled "Replacement Sheet" pursuant to 37 CFR 1.121(d).

Remarks

Applicants have carefully considered this Application in connection with the Examiner's Action, and respectfully request reconsideration of this Application in view of the foregoing amendment, and the following remarks.

Claims 1 – 7, 9 – 11, 20, 27-36 are pending. Claims 12 – 19 and 22 – 26 were canceled in light of the election of invention I and species (i) in the reply filed on May 2, 2008. Election is made with the proviso that non-elected species may be pursued in a continuation or divisional application.

Claims 8 and 21 are canceled by this amendment. Claims 1, 3, 5, 6, 7, 9, 11, and 20 are currently amended. New claims 27-36 are added.

Support for the amendments to claim 1 can be found in the claims and specification as filed. Specifically, support for "interconnecting porous configuration" can be found, for example, at paragraphs [0020] and [0046] of the published application. Support for "fibrous preform" can be found, for example, at paragraph [0025], [0031] and Example 1 of the published application. Support for pore sizes, such as nanopore, mesopores and macropores, can be found, for example, at paragraphs [0020], [0046], [0048], [0050] and [0051] of the published application. Support for "ranging in size from 1.5 to 10 nm" can be found at, for example, paragraph [0048] of the published application. Support for "surface area greater than 1000 m^2/g" can be found, for example, at paragraphs [0057] - [0058] and [0078] of the published application.

Support for the amendments to claims 6 and 7, specifically "bioactive agent" and bioactive agents recited at claim 7 can be found at, for example, paragraph [0054] of the published application.

Support for the amendments to claim 11, specifically support for "controlled release" and "release upon degradation" can be found at, for example, paragraph [0054] of the published application.

Support for newly added claim 27 can be found in the claims as originally filed, specifically support for claim 27 can be found, for example, in claim 7 and paragraph [0054] of the published application.

Support for newly added claims 28 and 31, specifically support for "the animal is a human" can be found at, for example, paragraph [0055] of the published Application.

Support for newly added claim 30, specifically "porous biomaterial implant," and the claim as a whole, can be found at, for example, paragraph [0055] of the published application.

No new matter has been added.

I ***Response to Rejection under 35 U.S.C. § 112, Second Paragraph***

Claims 3, 4, 9 and 10 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. In light of the amendments to claims 3 and 9, the rejection is moot. Specifically, regarding claims 9 and 10, the range of porous fibers which are hollow has been amended to provide a minimum percentage of 30%, rather than a range of at least 30% to 90%.

Applicants respectfully request that the rejection under § 112, second paragraph be withdrawn.

II ***Response to Rejection 1 under 35 U.S.C. § 102(b)***

Claims 1, 5-7, 11, 20 and 21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ahola *et al.* For the reasons discussed below, Applicants traverse the rejection.

With regard to claim 1, the Examiner cites Ahola for teaching a bioactive, biodegradable composite material of oxides and biodegradable polymers, wherein the fibers of the composite comprise gel-like oxide materials with nanometer-sized pores.

It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131 (quoting *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Therefore, Ahola must describe each and every element of the claims in order to anticipate under Section 102(b).

Applicant respectfully submits that, contrary to the Examiner's statement, Ahola fails to teach each and every element of Applicants' claims. Specifically, Ahola teaches a dissolvable silica-xerogel prepared via a sol-gel process. More specifically, Ahola teaches a xerogel composite by spray-drying or sol-spinning methods. (See Ahola, page 9, lines 5 – 35.) Thus, the

Ahola composite is not, and cannot be, considered to be self-assembled. Moreover, Ahola teaches a composite configuration of considerably smaller diameter, one comprising spheres and fibers, not outside of the nanopore range. (See Ahola, page 7, lines 25-33.) Ahola's configurations, specifically, woven or non-woven mats, filters, and fiber-mats are not self-assembled and all require additional assembly of silica-xerogel fibers previously produced in a separate step. (See Ahola, page 10, line 1, 13, and 16.) Thus, Ahola does not anticipate Applicants' claimed invention because it fails to disclose a self-assembled, 3-dimensional, fibrous composite preform comprising an interconnected porous network, expressly comprising a network of nanopores, mesopores and macropores, as recited in Applicants' claim 1.

Moreover, Ahola is devoid of any mention that the fibrous composite comprises an interconnected, multi-porous network configuration containing pores in a networked hierarchy of sizes. The teachings of Ahola do not anticipate the fibrous composite of Applicants' claims, since each and every element of the invention of Applicants' claims is not disclosed by the Ahola reference. (See, *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 91 (Fed. Cir. 1986), cert denied, 107 S. Ct. 1606 (1987) stating "Every element of the claimed invention must be identically shown in a single reference".)

As a result, Ahola fails to provide a fibrous composite preform and it fails to show a pore network ranging from nanopores, to mesopores, to macropores that in interconnected combination provide Applicants' fibrous composite material with a surface area greater than 1000 m^2/g – each of which is required in Applicants' application. As such, Ahola cannot, and does not, anticipate Applicants' claims 1, 5-7, 11, 20 and 21 under 35 U.S.C. §102 (b). Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

III ***Response to Rejection 2 under 35 U.S.C. § 102(b)***

Claims 1 – 3, 5 – 8, 11, 20 and 21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bellantone *et al.* The Examiner cites Bellantone for disclosing a bioactive, biodegradable composite material comprising a fibrous composite of oxides and biodegradable polymers, wherein fibers of the composite comprise oxide materials with nano-sized pores. For similar reasons as discussed above, Applicants traverse the rejection.

Bellantone fails to teach Applicants' claimed invention, as disclosed in Applicants' amended claim 1. Bellantone teaches silver-containing bioactive-glass composites prepared by a

sol-gel method. (See Bellantone Col. 2, lines 50-55 and Col. 4, lines 30-35.) Thus, the fibers of the composite of Bellantone are not a self-assembled fibrous preform, as required by Applicants' claim 1. Rather, Bellantone's mesh, fabric (woven or non-woven), mats, and three-dimensional structures all require an additional assembly of individual fibers produced by a previous separate step. (See Bellantone, 7, line 8, 17, 20, 23.) For example, in one embodiment, the Bellantone fibers are woven into mats or other structures. (See Bellantone, 7, line 20).

Moreover, while the Examiner cites Bellantone for teaching a fibrous composite having mesopores and macropores, no where does Bellantone teach an interconnected multi-porous network configuration as defined in the invention of Applicants' claim 1. Particularly, the Examiner cites Bellantone at col. 6 for teaching various pore sizes. Bellantone, however, at col. 6, lines 35 -40, actually discloses further processing techniques that may be applied to adjust the pore volume of the already-formed composite. Thus, any additional pore size or structure in the Bellantone composite, other than nanopores, is necessarily created by a post-formation modifications that require addition processing, such as sintering and/or foam processes. (See Bellantone, Col 6, lines 38-39.)

Consequently, the teachings of Bellantone do not anticipate the self-assembled multi-porous fibrous composite preform of Applicants' claims, since each and every element of the invention of Applicants' claims are not disclosed by the Bellantone reference. As such, Bellantone cannot anticipate claims 1-3, 5-7, 11, 20 and 21 under 35 U.S.C. §102(b). Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

IV Response to Rejections under 35 U.S.C. § 103(a)

Claims 2 and 3 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ahola *et al.*, in view of Hench *et al.* Claim 4 stands rejected under § 103(a) over Ahola, in view of Hench, and further in view of Li *et al*, and over Bellantone in view of Li. Claims 9 and 10 stand rejected under § 103(a) as being unpatentable over Ahola and/or Bellantone, in view of Beaver *et* al., and further in view of Slivka. For reasons similarly stated above in the rejection under 35 U.S.C. § 102(b), Applicants respectfully traverse these rejections.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As stated above regarding Applicants' claim 1, neither Ahola nor Bellantone teaches or suggests, even if combined, each and every element of Applicants' claimed invention because neither teaches a self-assembled fibrous composite preform, and they fail to show an interconnected pore network of pores ranging from nanopores, to mesopores, to macropores as are defined by Applicants' claimed fibrous composite, and system and methods of use therefore. Advantageously, Applicants' interconnected pore network creates a surface area greater than 1000 m^2/g, which is far greater than the resulting surface area in any of the cited prior art. As shown by the lack of any defined intervening step in Applicants' specification, the interconnected multi-porous arrangement of fibers self-assemble in Applicants' fibrous preform. Such a fibrous preform is not possible in either the Ahola or Bellantone inventions, alone or combined, because each require specific steps either pre- or post-formation that would preclude the formation of Applicants' preform. See foregoing arguments regarding anticipation rejections.

The Examiner cites additional art in an attempt to show that one skilled in the art would have been motivated to modify the compositions of Ahola and Bellantone to include other oxides (Hench), or disclose OH groups being silanol (Li) or other metal-OH groups, or to modify the porous fibers to be hollow (Beaver) to aid in cell and tissue infiltration (Slivka). Nevertheless, the additional teachings, even in combination with Ahola or Bellantone, also fail to teach or suggest each and every element of Applicants' claimed invention and do not cure the defects or Ahola and/or Bellantone. The additional cited references also fail to teach or suggest Applicants' multi-porous arrangement of networked fibers in a fibrous preform, comprising an interconnecting network of nanopores, mesopores and macropores.

Even if one skilled in the art were to modify Ahola or Bellantone as suggested by the Examiner, the resulting fibrous composites still fail to teach or suggest Applicants' claimed invention. The cited art of Bellantone states that the adjustment of pore size within a composite comprising spheres or fibers can be achieved by application of a sintering and/or foaming

process following completion of the sol-gel process. (See cols 5 and 6, specifically lines 35-40 of col 6, of Bellantone which detail the many steps involved in preparing their composite materials.) Applicants' claimed invention, however, neither teaches nor suggests a need for additional processing steps, such as sintering and/or foam processes to achieve a networked multi-porous fibrous configuration. To the contrary, without the need for any additional steps or processes, Applicants' fibers self-assemble into an interconnected-porous configuration, or preform, as exemplified at Applicants' Example 1 which details initial formation of silica fibers within an emulsion comprised of cationic and anionic materials. (See Applicants' Example 1: Method of Preparing and Testing Fibrous Silica Composites.)

Thus, Applicants' assert that alone, or in combination, the art cited by the Examiner fails to teach or suggest each and every one of the expressly required elements of Applicants' claimed invention. Accordingly, Applicants respectfully request the rejection under 35 U.S.C. §103(a) be reconsidered and withdrawn.

IV Conclusion

In view of the foregoing, Applicants' claims are in condition for allowance, and Applicants earnestly solicit a Notice of Allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this Application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

Evelyn H. McConathy

Date: October 1, 2008

Evelyn H. McConathy
Registration No. 35,279
MONTGOMERY, McCRACKEN,
WALKER & RHOADS, LLP
123 South Broad Street
Philadelphia, PA 19109-1099
Tel: (215) 772.7550
Fax: (215) 772.7620